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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ORGANOGENESIS, INC.,

Plaintiff,

-against-

ADVANCED BIOHEALING, INC.,

Defendant.

Civil Action No. 08 cv 00875(AKH)
Hon.

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION AND EXPEDITED DISCOVERY

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PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION AND EXPEDITED DISCOVERY

Plaintiff, Organogenesis, Inc., ("Plaintiff" or "OI") by and through counsel, moves for a temporary restraining order and an order preliminarily enjoining Defendant Advanced BioHealing, Inc. ("Defendant" or "Advanced BioHealing") from disseminating false, malicious and defamatory advertising directed to Plaintiff's customers, and from unfairly competing with Plaintiff in any other manner. In support, Plaintiff submits this memorandum along with attached Declarations of Patrick Bilbo, OI's Vice President, Regulatory Affairs, and Savalle C. Sims, Esquire, which are submitted as Exs. 1 and 2, respectively, with documentary evidence, and will show the Court as follows.

I. INTRODUCTION

OI requires the Court's immediate intervention to protect OI from Advanced BioHealing's further dissemination of a false and misleading advertising campaign targeting OI's customers and other wound-care providers. OI is the manufacturer of Apligraf, a skin regenerative product. In late 2007, Apligraf was subject to a very limited recall in which 177 units were potentially contaminated, after which OI promptly notified all potentially affected OI Apligraf customers.

On or about January 8, 2008, Advanced BioHealing, OI's direct competitor, began disseminating an e-mail communication to physicians in New York and other states attaching the Apligraf recall letter that OI sent to its customers. That e-mail falsely implies that Advanced BioHealing failed to contact all potentially affected physicians, and makes numerous false claims touting the alleged superiority of Advanced BioHealing's Dermagraft product. OI immediately requested Advanced BioHealing to cease disseminating such communications. Advanced BioHealing initially indicated that all such communications had ceased, but shortly thereafter OI learned that Advanced BioHealing, despite its representations to the contrary, had begun disseminating a second communication to OI's customers and potential customers that likewise attaches the Apligraf recall letter and falsely implies that Apligraf is unsafe.

Advanced BioHealing's actions have caused widespread confusion and deception among OI's consumers regarding the safety of Apligraf and the scope of the Apligraf recall. A number of Apligraf customers have contacted OI to express confusion as to whether they received the affected Apligraf units and to return Apligraf units that were not affected by the recall. As such, Advanced BioHealing's actions have interfered with OI's ability to effectuate the recall and have eroded OI's relationships with its customers. Without the Court's immediate intervention to halt Advanced BioHealing's actions, OI's Apligraf brand, its Apligraf recall effort, and its

relationships with Apligraf customers will be irreparably damaged.

II. STATEMENT OF FACTS

OI was founded in 1985. *See* Declaration of Patrick Bilbo in Support of Motion for Temporary Restraining Order and Motion for Preliminary Injunction, at ¶ 3 (hereinafter, "Bilbo Dec."). OI is a pioneer in the field of regenerative medicine and is a leading regenerative medicine company. *Id.* It researches and develops regenerative medicine technologies to deliver living, cell-based products to stimulate the body's natural healing process and activate the body's ability to repair and regenerate. *Id.*

OI is the manufacturer, distributor, and owner of all rights in Apligraf® ("Apligraf"). *Id.* at ¶ 4. Apligraf is biological tissue derived from human skin cells that, similar to human skin, contains two types of cells – an outer layer of protective skin cells (epidermal cells), and an inner layer of cells (dermal cells), both of which contain proteins and other substances that initiate the healing process. *Id.* Apligraf is able to help heal and repair chronic sores and regenerate skin by stimulating the body's healing process. *Id.* It delivers these biological healing substances (living cells and active proteins) directly into the wound thereby starting the healing cycle. *Id.*

After years of research and development, in 1998, OI received the first ever Food and Drug Administration ("FDA") approval for a manufactured living cell-based therapy, Apligraf, intended for the treatment of venous leg ulcers. *Id.* at ¶ 5. In 2000, FDA approved Apligraf for the treatment of diabetic foot ulcers. *Id.* Currently, Apligraf is the only bio-active product that is approved by the FDA to treat both chronic diabetic foot ulcers and venous leg ulcers. *Id.*

Diabetic foot ulcers and venous leg ulcers are conditions that often affect the elderly, Type II diabetics, or patients suffering from peripheral vascular disease. *Id.* at ¶ 6. Apligraf has been hailed a miracle of science and has changed the lives of patients suffering from such

chronic skin ulcers. *Id.* Prior to Apligraf, skin ulcers that would not respond to traditional wound treatment would often progress to a limb amputation or life threatening condition. *Id.* Apligraf has not only helped improve a patient's quality of life, but in many cases, it has saved a patient who otherwise may have lost a limb or succumbed to a life-threatening infection. *Id.*

Apligraf is a prescription product that must be applied to directly to a wound by a medical professional. *Id.* at ¶ 7. OI has invested significant resources towards building a highly skilled sales and marketing organization dedicated to Apligraf. *See* Bilbo Dec., Ex. 1. To date, over 200,000 patients have been treated with Apligraf. Bilbo Dec., at ¶ 7. Apligraf customers primarily consist of physicians, podiatrists, hospitals, and wound care treatment centers and clinics. *Id.* at ¶ 8.

THE APLIGRAF RECALL

In December 2007, OI learned that two packaging lots of Apligraf containing a total of 177 distributed Apligraf units were potentially contaminated (the "Affected Apligraf Units"). Bilbo Dec., at ¶ 9. Upon learning of the potential contamination, OI promptly designed and implemented a recall procedure for the Affected Apligraf Units in consultation with the FDA (the "Apligraf Recall"). *Id.* at ¶ 10.

In conducting the Apligraf Recall, OI identified all customers who had received the Affected Apligraf Units. *Id.* at ¶ 11. OI then contacted only those customers who received the Affected Apligraf Units to ensure OI's ability to properly and effectively track the Apligraf Recall. *Id.* Conducting a targeted recall also facilitates OI's ability to assist its Apligraf customers in monitoring the impact of any Affected Apligraf Units that may have been administered to patients. *Id.*

OI sent a letter to each of its customers who had received the Affected Apligraf Units (the "Apligraf Recall Letter"). *Id.* at ¶ 12. The Apligraf Recall Letter discloses the reason and clinical implications for the Apligraf Recall, provides contact information in the event of questions, and requests that the recipient provide OI with written confirmation of receipt of the Apligraf Recall Letter. *See* Bilbo Dec., Ex. 2. Indeed, the Apligraf Recall Letter makes it clear that it is *only* being sent to an Apligraf customer who received the Affected Apligraf Units. *See id.* The Apligraf Recall Letter further advises physicians who received the Affected Apligraf Units regarding the clinical implications of the Apligraf Recall:

> While the unit(s) you have received may not be contaminated, all standard wound care precautions should be used to assure the safety of the patient. If the affected units had been applied to a patient, it is recommended that you monitor the patient closely for any potential adverse events. Organogenesis recommends careful assessment of possible infection by observing for signs and symptoms of infection as well as treatment per your clinical discretion. **Treatment options at your discretion include topical antibiotics, oral antibiotics or Apligraf removal.** We hope that this information is helpful in managing care for your patient.

Id. at pp. 1-2 (Emphasis Added).

ADVANCED BIOHEALING'S FALSE AND MISLEADING ADVERTISEMENTS

Defendant Advanced BioHealing, which upon information and belief was recently founded in 2003, is a direct competitor of OI's Apligraf product. Bilbo Dec., at ¶ 15. Upon information and belief, Advanced BioHealing distributes and sells Dermagraft®, a product used for the treatment of wounds such as certain diabetic foot ulcers and wounds associated with dystrophic epidermolysis bullosa. *Id.* Upon information and belief, Dermagraft is not FDA approved for the treatment of venous leg ulcers.

On or about January 8, 2008, Advanced BioHealing sent out an electronic mail communication to at least one physician in the New York area. A copy of the electronic mail message is attached as Exhibit 3. *Id.* at ¶ 16. The electronic mail communication (the

"Advanced BioHealing Communication"), which was sent by Advanced BioHealing to wound care providers states:

> Wound Care Provider,
>
> I am sending a safety notification to all wound care providers that use multiple advanced wound care products in their practice. (Letter attached) This letter was sent directly from Organogenesis to many of their Apligraf customers throughout the country, but evidently not everyone. The letter outlines specific instructions to the physician. I am sending this letter in hopes that none of the contaminated Apligraf was applied to your patients.
>
> A reminder Dermagraft is the only cyro-preserved human-derived dermal substrate available. The advantages of cyro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves no chance for contamination and 100% confidence in safety for your patients' wounds.
>
> Proprietary cryopreservation process ensures confidence
> Dermagraft is cryopreserved to allow long-term maintenance of tissue integrity and cellular viability. Cryopreservation of Dermagraft offers a number of additional product benefits:
> · Allows for safety testing prior to shipping and application
> · Provides longer shelf life—long-term storage (up to 6 months) when stored at -75°C ± 10°C
> There have been no reported immunological responses or rejections from patients that received Dermagraft.
>
> Andrew Sole
> Advanced Technolgy Specialist-New York
> Advanced BioHealing, Inc.
> Direct: 732 991-3610
> Email: <mailto:lmyers@advancedbiohealing.com>
> asole@advancedbiohealing.com
> Orders: 1-877-DERMAGRAFT (877-337-6247)

Id. at ¶ 17. OI obtained a copy of the Advanced BioHealing Communication from two physicians located in New York on or about January 9, 2008. *Id.* at ¶ 18. Upon information and

belief, Advanced BioHealing also sent out the Advanced BioHealing Communication to physicians and other wound care professionals throughout the United States including, Florida, Michigan, New York, and Virginia. *Id.* at ¶ 19. Upon information and belief, in addition to circulating the Advanced BioHealing Communication by electronic mail message, Advanced BioHealing has also sent its representatives to a number of wound care treatment centers to disseminate the Advanced BioHealing Communication in person to physicians and nurses. *Id.* at ¶ 20. Additionally, Apligraf customers have reported to OI that Advanced BioHealing sales representatives have made various oral statements to Apligraf customers consistent with the Advanced BioHealing Communication. *Id.* at ¶ 21.

Upon learning of the Advanced BioHealing Communication, OI immediately advised Advanced BioHealing of the false claims contained in the Advanced BioHealing Communication and requested that Advanced BioHealing stop further dissemination of the Advanced BioHealing Communication. *See* Bilbo Dec., Ex. 4. Initially, Advanced BioHealing stated that it would investigate OI's claims. *See id.*, Ex. 5. Later, on or about January 14, 2008, Advanced BioHealing indicated that it had ceased disseminating communications regarding the Apligraf Recall as of January 9 or 10, 2008, and would continue to do so while the parties' discussed the possibility of settlement. *Id.* at ¶ 24.

ADVANCED BIOHEALING CONTINUES AND ESCALATES ITS WRONGFUL CONDUCT

On or about January 16, 2008, OI learned that Advanced BioHealing may not have ceased disseminating communications regarding the Apligraf Recall. *Id.* at ¶ 25. More specifically, OI received an electronic mail message from one of its customers that appeared to indicate that an Advanced BioHealing employee, Carol Gray, was attempting to recall an electronic mail message on January 14, 2008. *Id.* at ¶ 26.

OI promptly contacted Advanced BioHealing through counsel. *See* Bilbo Dec., Ex. 6. In response, Advanced BioHealing *now* assured OI, in writing, that it notified its sales force to ceased sending communications regarding the Apligraf Recall as of January 11, 2008. *Id.* at ¶ 28. A copy of Advanced BioHealing's correspondence from counsel is attached as Exhibit 7. On January 18, 2008, OI learned definitively that Advanced BioHealing had not ceased disseminating communications regarding the Apligraf Recall as of January 9, 10 or 11, 2008 despite Advanced BioHealing's representations to the contrary. *Id.* at ¶ 29.

Indeed, OI learned that on or about January 14, 2008, Advanced BioHealing sent out another electronic mail communication to OI's customers and other wound-care providers (the "Additional Advanced BioHealing Communication"). *See* Bilbo Dec., Ex. 8. The Additional Advanced BioHealing Communication contained the subject line "Copy of the Recent Apligraf Recall Letter, Unparalled [sic] Safety Profile of Dermagraft" and stated as follows:

> "Keeping You Informed:
>
> Attached is the letter announcing the recent Apligraf recall from Organogenesis. Apligraf recalls have happened many times. (as reported to the FDA and documented on the FDA website).
>
> *Dermagraft has an unparalleled safety profile*:
> Advanced Biohealing, Inc. will not send any Dermagraft to customers, for use on their patients, until the End of Production- USP Sterility Data Testing Results are completed (conducted by an independent laboratory):
> ~end of production USP Sterility Safety testing is a requirement *before* patient application with Dermagraft. Dermagraft has a 5 month shelf life.
> ~end of production USP Sterility Safety testing results for Apligraf are not obtained until *after* application to patients receiving Apligraf. This may put patients and their providers at risk.
>
> *Apply Dermagraft with confidence! Safety Unparalleled!*
>
> Carol Gray
> Advanced Technology Specialist
> Mobile: 443 306 4762
> EMail: cgray@advancedbiohealing.com"

OI obtained a copy of the Additional Advanced BioHealing Communication from one of its Apligraf customers. *Id.* at ¶ 32.

ADVANCED BIOHEALING HAS INTERFERED WITH THE APLIGRAF RECALL THEREBY JEOPARDIZING PUBLIC HEALTH

Advanced BioHealing's actions have unnecessarily expanded the scope of the Apligraf Recall and interfered with the administration of the Apligraf Recall, thus jeopardizing public safety and health. *Id.* at ¶ 33. As discussed, OI has advised Apligraf customers who received the Affected Apligraf Units regarding treatment options available to them including the administration of topical antibiotics, oral antibiotics or Apligraf removal. *Id.* at ¶ 34. Apligraf removal involves subjecting a patient to an additional surgical procedure. *Id.* At least one physician who received an Affected Apligraf Unit has opted to surgically remove the Apligraf unit. *Id.* at ¶ 35. Surgical removal of an Apligraf unit involves debriding (*i.e.*, scraping) the Apligraf off the wound in a surgical, sterile operating field. *Id.* It is conceivable that other physicians that have erroneously received the Advanced BioHealing Communication may subject their patients to unnecessary surgery as a result of confusion caused by Advanced BioHealing's actions. *Id.* at ¶ 36.

Further, Advanced BioHealing's conduct has unnecessarily expanded the scope of the Apligraf Recall from a relatively narrow recall of approximately 177 Apligraf units to potentially thousands of Apligraf units. *Id.* at ¶ 37. As a result, OI has had to devote its efforts to not only addressing inquires from customers who received the Affected Apligraf Units, but also fielding inquires and receipt forms from those Apligraf customers who did **not** receive the Affected Apligraf Units. *Id.*

Advanced BioHealing's actions have resulted in numerous calls to OI's customer service and medical inquiries department by customers who are not affected by the Apligraf Recall. *Id.* at ¶ 38. According to an Apligraf salesperson, the Advanced BioHealing Communication has also incited "panic" at one of her Apligraf customer's wound care treatment facilities. *Id.* at ¶ 39. As such, Advanced BioHealing's actions have irreparably harmed OI in that Advanced BioHealing has caused widespread marketplace confusion regarding Apligraf and the Apligraf Recall. *Id.* at ¶ 40. Advanced BioHealing has also unnecessarily caused Apligraf customers to unnecessarily question whether they have received the Affected Apligraf Units creating the possibility that patients will needlessly be subjected to painful surgery or other unnecessary clinical treatment. *Id.* at ¶ 41. Advanced BioHealing's actions have also potentially damaged the Apligraf Brand. *Id.* at ¶ 42.

THE ADVANCED BIOHEALING COMMUNICATION AND THE ADDITIONAL ADVANCED BIOHEALING COMMUNICATION HAVE CONFUSED AND DECEIVED APLIGRAF CUSTOMERS

The content of the Advanced BioHealing Communication and the Additional Advanced BioHealing Communication strongly suggest that the communication is directed to current and potential Apligraf customers. Bilbo Dec., at ¶ 43. A number of Apligraf customers have contacted and continue to contact OI to inquire about whether they received the Affected Apligraf Units and to express concern and confusion as to whether their patients received the Affected Apligraf Units. *Id.* at ¶ 44. For example, after Advanced BioHealing disseminated the Advanced BioHealing Communication to nurses at a wound treatment center in New York, "panic" ensued as the nurses attempted to determine whether their patients were affected by the Apligraf Recall. *Id.* at ¶ 45. It was reported to an OI Apligraf sales representative that the nurses were confused by the Advanced BioHealing Communication and concerned about the impact of the Apligraf Recall on their patients. *Id.* They proceeded to "frantically" rifle through

patient files to determine if they received the Affected Apligraf Units. *Id.* The nurses were further concerned and confused as to why they had not received notification from OI regarding the Apligraf Recall. *Id.*

Additionally, after receiving the Advanced BioHealing Communication, a number of Apligraf customers have contacted OI to (1) express confusion as whether they received the Affected Apligraf Units; (2) return Apligraf units that are not impacted by the Apligraf Recall; and (3) return written receipt of the Apligraf Recall Letter despite the fact that they did not receive Affected Apligraf Units. *Id.* at ¶ 46. Due to confusion associated with the Advanced BioHealing Communication, OI had to provide two of the largest national wound care chains, with hundreds of facilities across the United States, with clarification of the Apligraf Recall including a written summary of the Apligraf Recall, a summary of OI's actions with respect to the Apligraf Recall, and explanation of the relevance of the Advanced BioHealing Communication to the Apligraf Recall. *Id.* at ¶ 47.

Upon information and belief, the Additional Advanced BioHealing Communication has also damaged OI's relationships with consumers by suggesting that Apligraf is not safety-tested prior to distribution. *Id.* at ¶ 48.

THE MISLEADING AND FALSE CLAIMS

The Advanced BioHealing Communication is false and misleading in that purports to be a "safety notification." Bilbo Dec., at ¶ 49. The Advanced BioHealing Communication also is misleading in that it implies that OI selectively and improperly sent out the Apligraf Recall Letter to only certain Apligraf customers. *Id.*, at ¶ 50. This claim is misleading because OI sent out the Apligraf Recall Letter to all Apligraf customers who received the affected Apligraf Units pursuant to an FDA approved recall protocol. *Id.* Further, OI sent the Apligraf Letter directly to

the treating physician who received the Affected Apligraf Unit to ensure the smooth administration of the Apligraf Recall and to minimize the possibility that multiple letters would be sent to multiple individuals within a wound care treatment practice. *Id.*

The Advanced BioHealing Communication claims that "the advantages of cyro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves *no chance for contamination and 100% confidence in safety* for your patients' wounds." (Emphasis Added). *See* Bilbo Dec., Ex. 2. These claims are false because the Food and Drug Administration ("FDA") does not conduct sterility testing or any type of testing. Bilbo Dec., at ¶ 52. These claims also are false because Dermagraft underwent a recall in 1998 for endotoxin contamination levels that did not meet FDA standards and a 2003 recall for distributed product that did not meet specifications. *See* FDA Enforcement Report dated May 20, 1998 for Dermagraft and a related product, Dermagraft-TC, attached as Bilbo Dec., Ex. 9. *See also* FDA Enforcement Report dated June 11, 2003 for Dermagraft attached as Bilbo Dec., Ex. 10.

The Advanced BioHealing Communication claims that cryo-preservation of Dermagraft "allows for safety testing prior to shipping and application". *See* Bilbo Dec., Ex. 2. This claim misleadingly implies that Apligraf is not safety tested prior to release. Bilbo Dec., at ¶ 53. This claim is misleading and false in that OI has rigorous internal standards to ensure compliance with applicable FDA standards and regulations. *Id.*

The Additional Advanced BioHealing Communication

The Additional Advanced BioHealing Communication contains a number of misleading statements. *Id.* at ¶ 54. For instance, the Additional Advanced BioHealing Communication misleadingly implies that Apligraf's safety record and/or safety protocol place wound care

practitioners and patients at risk. *Id.* The Additional Advanced BioHealing Communication also misleadingly implies that Apligraf is not safety-tested until after it is applied to patients. *Id.* at ¶ 55.

III. ARGUMENT

Advanced BioHealing's false and deceptive claims are precisely the type of claims that the Lanham Act is intended to reach, because they strike at the heart of the competitive process. Indeed, Congress enacted Section 43(a) of the Lanham Act "to stop the kind of unfair competition that consists of lying about goods or services." *U-Haul Int'l, Inc. v. Jartran, Inc.*, 681 F.2d 1159, 1162 (9th Cir. 1982). In the name of honesty and fair play, this Court should enter an injunction against Advanced BioHealing prohibiting it from further dissemination of these blatantly false and misleading advertisements.

A. STANDARD FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

The standard for granting a temporary restraining order and a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure are identical. *AIM Int'l Trading, LLC v. Valcucine S.p.A.*, 188 F. Supp. 2d 384, 386 (S.D.N.Y. 2002). It is well-established that in order to obtain such relief, "the movant must show (a) irreparable harm and (b) either (1) likelihood of success on the merits or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly toward the party requesting the preliminary relief." *Id.* at 387 (*citing Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979)). Irreparable harm will be presumed where a plaintiff demonstrates a likelihood of success in showing a literally false comparative advertisement mentions plaintiff's product by name. *See Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62

(2d Cir. 1992). Moreover, where, as here, "the defendant[] make[s] false comparative advertising claims and the parties are direct competitors, irreparable harm is presumed to result from the continued dissemination of the advertising." *Gillette Co. v. Wilkinson Sword, Inc.*, No. 89 CIV. 3586 (KMW), 1989 WL 82453, at *1 (S.D.N.Y. July 6, 1989) (*citing McNeilab, Inc. v. Am. Home Prods. Corp.*, 848 F.2d 34, 38 (2d. Cir. 1988)). As set forth below, every one of these factors weighs in favor of the injunctive relief sought by OI against Advanced BioHealing's false advertising.

B. OI HAS ESTABLISHED A LIKELIHOOD OF SUCCESS ON THE MERITS OF ITS CLAIMS

As shown below, OI clearly meets its burden of showing that it will likely prevail on the merits of its claims for false advertising under the Lanham Act, as alleged in its Complaint. At the very least, OI has shown that there is a sufficiently serious question regarding the merits and that the balance of hardships favors OI.

1. OI Is Entitled to Relief Under Section 43(a) of the Lanham Act.

As pertinent here, Section 43(a) of the Lanham Trademark Act, 15 U.S.C. § 1125(a) (the "Lanham Act"), provides:

> (1) Any person who, on or in connection with any goods or services . . . uses in commerce any word, term, name, symbol or device, or any combination thereof, or any . . . false or misleading description of fact, or false or misleading representation of fact, which - -
>
> . . . .
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her . . . goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a).

To satisfy its burden of demonstrating a likelihood of success on the merits of its claim for false advertising under Section 43(a), OI must show that the Advanced BioHealing Communication is either (1) literally false or (2) although literally true, likely to deceive or confuse consumers. *See Johnson & Johnson-Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir. 1992). Further, although an advertisement may be literally true, a Court may deem it false by necessary implication if it is susceptible to no more than one interpretation. *See Gillette Co.*, 1989 WL 82453 at *2. In this case, the Advanced BioHealing Communication is both literally false and likely to deceive or confuse consumers.

C. THE ADVANCED BIOHEALING COMMUNICATION IS LITERALLY FALSE.

If an advertising claim is "literally, explicitly or unambiguously false on its face, a court may enjoin the defendant from disseminating or otherwise using the claim, regardless of the claim's effect on the consuming public." *Tambrands, Inc. v. Warner-Lambert Co.*, 673 F. Supp. 1190, 1193 (S.D.N.Y. 1987); *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991) (where defendant's claims are literally false, "the court may enjoin the use of the claim 'without reference to the advertisement's impact on the buying public'") (citation omitted).

The Advanced BioHealing Communication makes two claims that are literally, explicitly and unambiguously false. First, the Advanced BioHealing Communication states that "Dermagraft goes through 14 day sterility testing by the FDA before it is shipped. This leaves no chance for contamination and 100% confidence in safety for your patients' wounds." Bilbo Dec., Ex. 2. The claim that Dermagraft is sterility tested by the FDA is literally false. The FDA does not conduct sterility testing, or any other kind of testing. Bilbo Dec., at ¶ 52.

Second, the claim that there is "no chance for contamination" of Dermagraft is literally false. This claim is false because Dermagraft underwent a recall in 1998 for endotoxin levels that did not meet FDA standards and a 2003 recall for distributed product that did not meet specifications. *See* FDA Enforcement Report dated May 20, 1998 for Dermagraft attached as Bilbo Dec., Exhibit 9. *See also* FDA Enforcement Report dated June 11, 2003 for Dermagraft attached as Bilbo Dec., Exhibit 10.

Because these claims are false on their faces, or "literally false," OI easily meets its burden of proving that Advanced BioHealing has violated Section 43 of the Lanham Act. *See Castrol Inc.*, 977 F.2d at 62; *see also United Indus. Corp. v. The Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir. 1998). As such, OI is likely to succeed on its claim that the Advanced BioHealing Communication is literally false.

a. The Advanced BioHealing Communication is Literally False Because it is False by Necessary Implication

The Second Circuit has adopted what is known as the "false by necessary implication" doctrine. *Time Warner Cable, Inc. v. DirectTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007) (citation omitted). Under that doctrine, "[i]f the words or images, considered in context, necessarily imply a false message, the advertisement is literally false and no extrinsic evidence of consumer confusion is required." *Id.*; *see also id.*, *quoting Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Pharm. Co.*, 290 F.3d 578, 586-87 (3d Cir. 2002) ("A literally false message may be either explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated.") (internal quotation marks omitted). In order to be deemed literally false by

necessary implication, the claim must be unambiguously false and not "susceptible to more than one reasonable interpretation." *Time Warner Cable, Inc.*, 497 F.3d at 158.

Here, the entire context of the Advanced BioHealing Communication renders several claims false by necessary implication. First, the Advanced BioHealing Communication states that the Apligraf Recall Letter was sent to "many of [OI's] Apligraf customers throughout the country, but apparently not all." Taken in the context of the entire e-mail, including the sender's representation that the e-mail is a "safety notification," Advanced BioHealing's use of the language "apparently not all" conveys the unmistakable message that OI sent the Recall Letter to some, but not all, customers affected by the Apligraf Recall. This claim is literally false by necessary implication, because OI sent out the Apligraf Recall Letter to all Apligraf customers who received the affected Apligraf Units pursuant to an FDA approved recall protocol. Bilbo Dec., at ¶ 50.

Second, the Advanced BioHealing Communication states that cryo-preservation (the technology used in its Dermagraft product) "allows for safety testing prior to shipping and application." *See* Bilbo Dec., Ex. 2. Given that the entire thrust of Advanced Beheading's communication is to falsely alarm recipients about the supposed risks associated with Apligraf, the unmistakable message of this claim is that Dermagraft is safety-tested but Apligraf is not. Such a claim is literally false by necessary implication because OI has rigorous internal standards to ensure compliance with applicable FDA standards and regulations. *See* Bilbo Dec., at ¶ 52.

Finally, the claim that Dermagraft undergoes "14 day sterile testing by the FDA," in addition to being literally false, also is false by necessary implication. This is because the claim implies that the FDA is actively involved in the Dermagraft manufacturing process, and that

Apligraf somehow fails to meet FDA standards. These claims are misleading and false because, as noted above, the FDA has no involvement in sterility testing and Apligraf is subject to rigorous internal testing by OI. *See* Bilbo Dec., at ¶ 52.

Consequently, the above claims are literally false by necessary implication and should be enjoined.

b. The Advanced BioHealing Communication and the Additional Advanced BioHealing Communication Are Likely to Deceive Consumers

The Advanced BioHealing Communication and the Additional Advanced BioHealing Communication contain claims that are impliedly false and misleading and are likely to cause consumer confusion, and therefore should be enjoined. An injunction is "appropriate under 15 U.S.C. § 1125(a)(2) if the plaintiff can establish a likelihood of confusion on the part of the public as a result of false or misleading descriptions of a product." *Next Plateau Records v. ZYX Records*, Nos. 92 Civ. 4622 (LJF), 92 Civ. 4661 (LJF), 1992 WL 177153, at *6 (S.D.N.Y. July 13, 1992). The question for the Court in reviewing an allegedly impliedly false advertising claim is "what does the person to whom the advertisement is addressed find to be the message." *Am. Brands, Inc. v. R.J. Reynolds Tobacco Co.*, 413 F. Supp. 1352, 1357 (S.D.N.Y. 1976). Again, the Court must consider the entire context in which the claim is made. *See Gillette Co.*, 1989 WL 82453 at *2 (review of allegedly implied false claim involves "examining the text of the advertisement within the context of the entire commercial"). In addition, where a plaintiff adequately demonstrates that a defendant has intentionally set out to deceive the public, and the defendant's deliberate conduct in this regard is of an egregious nature, a presumption arises that consumers are, in fact, being deceived. *Res. Developers, Inc. v. Statue of Liberty-Ellis Island Found., Inc.*, 926 F.2d 134, 140 (2d Cir. 1991).

As noted above, Advanced BioHealing claims that "apparently not all" Apligraf customers were notified of the Recall and that Dermagraft "allows for safety testing" are likely to mislead consumers because they suggest that falsely suggest that OI failed to contact potentially affected customers and that Apligraf does not allow for safety testing. Indeed, these claims have caused actual confusion among Apligraf customers. Specifically, Advanced BioHealing's actions have resulted in numerous calls to OI's customer service and medical inquiries department by customers who are not affected by the Apligraf Recall. Bilbo Dec., at ¶ 38. As a result, OI's ability to fully and accurately track and report with precision the effectiveness of the Apligraf Recall is hampered. *Id.* Moreover, according to an Apligraf salesperson, the Advanced BioHealing Communication has also incited "panic" at one of her Apligraf customer's wound care treatment facilities. *Id.* at ¶ 39. As such, Advanced BioHealing has caused Apligraf customers to unnecessarily question whether they have received the Affected Apligraf Units creating the possibility that patients will needlessly be subjected to painful surgery or other unnecessary clinical treatment. *Id.* at ¶ 41. Thus, it is indisputable that the Advanced BioHealing Communication is likely to cause, and indeed already has caused, confusion among Apligraf's customers. The Advanced BioHealing Communication therefore should be enjoined.

In a similar vein, the Additional Advanced BioHealing Communication contains a number of misleading statements. For instance, the Additional Advanced BioHealing Communication misleadingly implies that Apligraf's safety record and/or safety protocol place wound care practitioners and patients at risk. The Additional Advanced BioHealing Communication also misleadingly implies that Apligraf is not safety-tested until after it is

applied to patients, when such is not the case. Because these claims are likely to mislead consumers, they should be immediately enjoined.

Moreover, an injunction is eminently proper here because Advanced BioHealing intended to deceive the recipients of the Advanced BioHealing Communication and the Additional Advanced BioHealing Communication. Where a defendant intentionally sets out to deceive the public, a presumption arises that consumers are being deceived. *Res. Developers, Inc.* 926 F.2d at 140. Advanced BioHealing clearly knew at the time it disseminated the communication that its claims were false. In this regard, Advanced BioHealing certainly knew that its product had been subject to a recall, and that the FDA has no involvement in sterility testing. Thus, it knew that its claims that Dermagraft "leaves no chance for contamination" and that Dermagraft undergoes sterility testing by the FDA were false at the time it disseminated them. Advanced BioHealing's knowing use of false claims demonstrates its intent to pry customers away from OI by creating the false impression that Advanced BioHealing's product is safe and OI's product is not. Therefore, it should be presumed from Advanced BioHealing's conduct that customers have been misled and confused. *See S.C. Johnson & Son, Inc. v. Clorox Co.*, 930 F. Supp. 753, 780 (E.D.N.Y. 1996).

As the above demonstrates, there is no question that OI has satisfied its burden of showing that it will likely prevail on the merits of its claims against Advanced BioHealing. At the very least, OI has demonstrated that there are sufficiently serious questions going to the merits to make them a fair ground for litigation.

D. OI WILL BE IRREPARABLY HARMED IF DEFENDANT IS NOT ENJOINED

Advanced BioHealing cannot credibly question that OI will be irreparably harmed if Advanced BioHealing is not enjoined. In particular, OI's relationships with its customers, the

reputation of its Apligraf product, and the administration of the Apligraf Recall will be irreparably harmed if Advanced BioHealing is not enjoined.

OI has received inquiries from its Apligraf customers suggesting that Advanced BioHealing's actions have led OI's customers to question whether OI improperly failed to notify them of the Apligraf Recall. Bilbo Dec., at ¶ 46. The Advanced BioHealing Communication has also prompted Apligraf customers to unnecessarily question whether their patient's safety is impacted by the Apligraf Recall, thus increasing the likelihood that some patients may be needlessly exposed to needless clinical treatment. *Id.*, at ¶ 41.

Further, Advanced BioHealing's conduct has unnecessarily expanded the scope of the Apligraf Recall from a relatively narrow recall of approximately 177 Apligraf units to potentially thousands of Apligraf units. Bilbo Dec., at ¶ 37. As a result, OI has had to devote its efforts to not only addressing inquires from customers who received the Affected Apligraf Units, but also fielding inquires and receipt forms from those Apligraf customers who did **not** receive the Affected Apligraf Units. *Id.* Also, as discussed above, Advanced BioHealing's actions have irreparably harmed OI in that Advanced BioHealing has caused widespread marketplace confusion regarding Apligraf and the Apligraf Recall. *Id.* at ¶ 40.

Moreover, in light of the fact that OI and Advanced BioHealing are direct competitors, the potential harm from these false advertisements is clearly damaging to OI's business. *See Vidal Sassoon, Inc. v. Bristol-Myers Co.*, 661 F.2d 272, 278 (2d Cir. 1981) (where parties are direct competitors, there is a presumption that false advertising claims, "if repeatedly communicated to consumers, would eventually result in loss of sales to Sassoon" and thus "proof of diversion of sales is not required for an injunction to issue pursuant to § 43(a)"). Furthermore, the loss of reputation and goodwill that necessarily results from a false and

misleading advertising claim also constitutes irreparable injury under Section 43(a). *W.L. Gore & Assocs. v. Totes, Inc.*, 788 F. Supp. 800, 810 (D. Del. 1992). As discussed, *supra*, Advanced BioHealing's communication uses false and misleading claims to directly attack the Apligraf product.

If Advanced BioHealing's false advertising campaign is permitted to proceed now, the injury to the OI and the reputation of its Apligraf product will be even more substantial, and the Advanced BioHealing Communication therefore should be immediately enjoined.

E. BALANCE OF HARDSHIPS FAVORS OI

The evidence presented by OI clearly demonstrates that it has suffered and will continue to suffer damage in the marketplace as a result of Advanced BioHealing's false advertising. On the other hand, there is no real hardship to Advanced BioHealing resulting from the issuance of an injunction in this case, especially since Advanced BioHealing is free to correct its false advertising in a relatively inexpensive way, should it choose to do so at the present time rather than waiting for the outcome of an appeal. As such, the balance of hardships in this case tips decidedly in favor of OI. Indeed, it is difficult to envision any hardship that could be claimed by Advanced BioHealing.

F. THE PUBLIC INTEREST FAVORS INJUNCTIVE RELIEF

There is strong public interest in ensuring that consumers receive truthful information. *See, e.g., Alternative Pioneering Sys., Inc. v. Direct Innovative Prods.*, Inc., 822 F. Supp. 1437, 1444-45 (D. Minn. 1993); *W.L. Gore & Assocs., Inc.*, 788 F. Supp. at 813-14. In *Alternative Pioneering*, the court described this interest as follows:

> Consumers have a right not to be subjected to deceptive or confusing advertisements so that they can accurately assess the quality of a product and choose a product that is in accordance with their preferences . . . . False or misleading advertising deprives the public of that information and may lead them to make purchases they might not

> otherwise make if they were supplied with truthful information . . . . The public also has an interest in fostering open and fair competition.

Alternative Pioneering Sys., Inc., 822 F. Supp. at 1444-45. See also *Sanborn Mfg. Co. v. Campbell Hausfeld/Scott Fetzer Co.*, 997 F.2d 484, 490 (8th Cir. 1993).

Here, Advanced BioHealing's advertising is false and deceptive regarding OI's goods and attempts to deprive consumers of OI's Apligraf product. In addition, Advanced BioHealing's false and misleading advertising jeopardizes the public health and the administration the Apligraf Recall. This factor therefore weighs in favor of entry of the requested injunction.

G. OI SHOULD BE ENTITLED TO TAKE EXPEDITED DISCOVERY IN ADVANCE OF THE PRELIMINARY INJUNCTION HEARING

OI's Motion for Preliminary Injunction seeks to enjoin Advanced BioHealing from further dissemination of false and deceptive advertisements concerning the Apligraf Recall and from making false claims regarding Apligraf and the Apligraf Recall. This matter is extremely time sensitive because it is apparent that Advanced BioHealing has sent the Advanced BioHealing Communication and Additional Advanced BioHealing Communication to OI's customers and to other physicians and wound-care providers throughout the United States in a deliberate attempt to disparage OI's Apligraf product and unfairly compete with OI. *See* Sims Dec. at ¶ 3. Expedited discovery is critical in this instance in order to determine the full extent and intent of Advanced BioHealing's dissemination of the disparaging communications.

The Federal Rules for Civil Procedure give this Court broad discretion to order expedited discovery. *See Watson v. Miears*, 772 F.2d 433, 437 (8th Cir. 1985) (stating that "[t]rial judges have the responsibility and authority to expedite the discovery process"); *Soler v. G & U, Inc.*, 86 F.R.D. 524, 530-531 (S.D.N.Y. 1980). The traditional analysis used by this Court in reviewing requests for expedited discovery considers the following factors: (1) irreparable injury; (2) some probability of success on the merits; (3) some connection between expedited

discovery and the avoidance of the irreparable injury; and (4) some evidence that the injury that will result without expedited discovery looms greater than the injury that the defendant will suffer if the expedited relief is granted. *Notaro v. Koch*, 95 F.R.D. 403, 405 (S.D.N.Y. 1982). In recent decisions, however, this Court has adopted a more flexible standard of "reasonableness" and "good cause" in reviewing requests for expedited discovery. *See Stern v. Cosby*, No. 07 Civ. 8536(DC) 2007 WL 3261522 (S.D.N.Y. Nov. 6, 2007) (*quoting Ayyash v. Bank Al-Madina*, 233 F.R.D. 325, 326-27 (S.D.N.Y. 2005) ("this Court will assess the application [for expedited discovery] under the standard of reasonableness and good cause"). Moreover, expedited discovery is especially appropriate in cases, such as this, where a party is seeking injunctive relief. *See e.g., Ellsworth Assoc., Inc. v. United States*, 917 F.Supp. 841, 844 (D.D.C. 1996) (granting party's request for expedited discovery "because of the expedited nature of injunctive proceedings"); *Edudata Corp. v. Scientific Computers, Inc.* 599 F.Supp. 1084, 1088 (D. Minn. 1984) (stating that "[f]urther development of the record before the preliminary injunction hearing will better enable the court to judge the parties' interests and respective chances for success on the merits").

As discussed above, OI has established irreparable injury and a likelihood of success on the merits. Expedited discovery will allow OI to prevent further irreparable injury to its customer relationships and its implementation of the Apligraf Recall. *See* Declaration of Savalle C. Sims in Support of Motion for Temporary Restraining Order, Preliminary Injunction and Expedited Discovery, hereinafter "Sims Dec.," at ¶ 20. In this regard, expedited discovery will allow OI to discover the list of recipients to whom Advanced BioHealing sent the Advanced BioHealing Communication and the Additional Advanced BioHealing Communication and any other communications regarding Apligraf and the Apligraf Recall. *Id.* OI then will be able to

contact the affected customers in the interest of preserving its customer relationships and the integrity of the Apligraf Recall. *Id.* at ¶ 21. The expedited discovery also will verify Advanced BioHealing's intent in sending the communications, and will facilitate the preservation of evidence, and allow for an orderly presentation of testimony and evidence at the hearing on Advanced BioHealing's Motion for Preliminary Injunction. *Id.*

The injury that looms to OI is much greater than any inconvenience to Advanced BioHealing resulting from expedited discovery. The expedited discovery sought by OI prior to the hearing on its Motion for Preliminary Injunction will be narrowly tailored to the issue of Advanced BioHealing's dissemination of the Advanced BioHealing and Additional Advanced BioHealing Communications, and any other communications regarding the Apligraf Recall or containing false or deceptive claims, to OI's customers or to other physicians or wound-care providers. *See id.* at ¶ 22. OI also seeks to take the 30(b)(6) deposition of Advanced BioHealing's corporate designee regarding the documents that are produced, which likewise will assist in determining the full extent of the dissemination of the communications. *Id.* at ¶ 23.

Until OI has discovery from Advanced BioHealing on these issues, the full extent of harm and damage caused by Advanced BioHealing's deceptions and false statements will not be known. *Id.* at ¶ 24. As such, the Court should grant OI's Motion for Expedited Discovery in advance of the preliminary injunction hearing.

IV. CONCLUSION

For the foregoing reasons, OI respectfully requests that this Court grant its motion for a temporary restraining order, preliminary injunctive relief, and expedited discovery.

Dated: January 24, 2008
New York, New York

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